IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCE

In re Application of:	Robert Markes		
Title:	SAMPLING INSTRUMENT		
Serial No.:	10/659,291	Filing Date:	11 September 2003
Examiner:	Lyle Alexander	Group Art Unit:	1797

Mailstop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

BRIEF ON APPEAL

Sir:

Further to the Notice of Appeal filed electronically in the U.S.P.T.O. on January 22, 2010, in the above-identified application, Appellant hereby submits this Brief on Appeal. Authorized fees include the $270 fee for the filing of this Brief.

This is an appeal from the decision of the Examiner rejecting claims 1, 5-10 and 12-20 of the above-identified application.

(i) REAL PARTY IN INTEREST

The above-identified application is assigned of record to B.G. Negev Technologies & Applications Ltd., Reel 014497, Frame 0133, who is the real party in interest herein.

(ii) RELATED APPEALS AND INTERFERENCES

In accordance with 37 CFR §41.37(c)(1)(ii), Appellant advises the Board of Patent Appeals and Interferences (the "Board") that there are no other pending appeals, which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the instant

appeal.

(iii) STATUS OF THE CLAIMS

A statement of the status of all the claims, pending or canceled, and identifying the claims appealed:

Claims 1, 5-10 and 12-20 are now pending in the above-identified application.

Claims rejected: 1, 5-10 and 12-20

Claims allowed: none

Claims canceled: 2-4, 11

Claims withdrawn: 21

Claims on Appeal: Claims 1, 5-10 and 12-20 (Copy of claims on appeal, as amended, in attached Appendix).

(iv) STATUS OF AMENDMENTS

There were no amendments submitted after Examiner's last rejection.

(v) SUMMARY OF CLAIMED SUBJECT MATTER

Appellant's invention is directed to, *inter alia*, sensors for use in biological, microbiological, biochemical and chemical testing, and particularly to instruments and/or sensors used to monitor the presence of a substance, such as but not limited to, monitoring the interaction of antibodies with their corresponding antigens and for detecting the presence of antigens, for example, as described in Figures 1-2, and on pages 1-8 of the specification.

Instrument 10 may comprise a first housing 12 comprising a needle 14 arranged for protrusion therefrom. Needle 14 is adapted to draw therethrough a biological fluid 15, such as but not limited to, blood, lymph, saliva, sweat and the like. Needle 14 may be retractable into first housing 12. One or more reagents 16 may be disposed in one or more compartments 17 first housing 12 in fluid communication with needle 14. Reagent 16 may comprise any substance capable of producing an optically-sensible reaction with the biological fluid 15. An optical sensor 18 may be disposed in first housing 12 for sensing the optically-sensible reaction (specification, page 3, last paragraph, lines 27-34).

A processor 20 may be in communication with optical sensor 18, such as by means of one or more optical waveguides 22 (the term "optical waveguide" also encompasses an optical fiber). Processor 20 may process a signal from optical sensor 18, the signal being a function of the optically-sensible reaction. For example, processor 20 may comprise a microprocessor 24 and photodiode 26. Photodiode 26 may convert the light emission from optical waveguide 22 to a current and then to a display 28 in communication with processor 20. Any number and kind of control buttons 30 (e.g., on/off, display functions, command keys, etc.) may be provided (specification, page 4, first paragraph, lines 1-8).

Alternatively or additionally, a transmitter and/or receiver may be provided for wireless communication with an external processor, server, website, etc., such as but not limited to, radio transmission, cell phone transmission, infrared transmission and the like (specification, page 4, second paragraph, lines 9-11).

Processor 20 and display 28 may be disposed in a second housing 32. First and second housings 12 and 32 may together form an elongate housing. First and second housings 12 and 32 may comprise mating connectors 34 and 36, respectively, to effect the communication between processor 20 and optical sensor 18. First housing 12 may be disposable, whereas second housing 32 may be reusable (specification, page 4, third paragraph, lines 12-16).

Optionally fluid pump 38 may be in fluid communication with needle 14 to assist pumping and drawing the biological fluid 15 through needle 14. The fluid pump 38 may be disposed in second housing 32, but alternatively may be disposed in first housing 12 (specification, page 4, fourth paragraph, lines 17-19).

First housing 12 may also comprise a waste receptacle 40 for storing therein waste products of the optically-sensible reaction. Waste receptacle 40 may alternatively or additionally be used for storing therein a destructive fluid for neutralizing fluids, such as but not limited to, HIV or hepatitis inflected fluids and the like (specification, page 4, fifth paragraph, lines 20-23).

In operation of biological sampling instrument 10, as mentioned above, optical sensor 18 may sense the optically-sensible reaction of reagent 16 with biological fluid 15. For example, interaction of reagent 16 with an analyte in the biological fluid 15 specific to reagent 16 may produce a colored product, which is detectable by optical sensor 18 means of a change in characteristics of a light beam transmitted thereat. As such, biological sampling instrument 10 may further comprise a light source

42 of coherent or non-coherent light. Light source 42 may transmit a light beam to the reaction site via optical waveguide 22. Alternatively, light source 42 may be disposed in first housing 12. It is appreciated that the invention is not limited to this example, and other optical phenomena may be detected by a suitable optical sensor 18, such as but not limited to, surface plasmon resonance (SPR) (specification, page 4, last paragraph, lines 24-34).

Claim 1 recites a sampling instrument comprising a first housing comprising a needle arranged for protrusion therefrom, said needle being adapted to draw therethrough a fluid (specification, page 3, last paragraph, lines 27-28); a reagent disposed in said first housing in fluid communication with said needle, capable of producing an optically-sensible reaction with a fluid (specification, page 3, last paragraph, lines 30-33); an optical sensor disposed in said first housing adapted to sense said optically-sensible reaction (specification, page 3, last paragraph, lines 33-34); a first optical waveguide in said first housing connected to said optical sensor (specification, page 4, first paragraph, lines 1-2) and to a first optical connector (specification, page 4, third paragraph, lines 13-15); and a processor disposed in a second housing in communication with said optical sensor adapted to process a signal from said optical sensor (specification, page 4, first paragraph, lines 1-2), said signal being a function of said optically-sensible reaction (specification, page 4, first paragraph, line 4), wherein said processor comprises a microprocessor and a photodiode (specification, page 4, first paragraph, lines 4-5), said processor being connected to a second optical waveguide disposed in said second housing (specification, page 4, third paragraph, line 12), said second optical waveguide being connected to a second optical connector which mates with said first optical connector so as to effect optical communication between said processor and said optical sensor (specification, page 4, third paragraph, lines 13-15), wherein said photodiode is adapted to convert light emission transmitted thereto from said optical waveguide to a current (specification, page 4, first paragraph, lines 5-6).

Claim 5 further recites that said first housing is disposable (specification, page 4, third paragraph, lines 15-16).

Claim 6 further recites a fluid pump in fluid communication with said needle adapted to pump a biological fluid through said needle (specification, page 4, fourth paragraph, lines 17-18).

Claim 7 further recites a fluid pump in fluid communication with said needle adapted to pump a biological fluid through said needle, wherein said fluid pump is disposed in said second housing (specification, page 4, fourth paragraph, lines 17-19).

Claim 8 further recites that said first housing comprises a waste receptacle for storing therein waste products of said optically-sensible reaction (specification, page 4, fifth paragraph, lines 20-21).

Claim 9 further recites that said needle is retractable into said first housing (specification, page 3, last paragraph, lines 29-30).

Claim 10 further recites a display in communication with said processor (specification, page 4, first paragraph, lines 6-7).

Claim 12 further recites at least one of a transmitter and a receiver for wireless communication with an external device (specification, page 4, second paragraph, lines 9-10).

Claim 13 further recites that said first and second housings together form an elongate housing (specification, page 4, third paragraph, lines 12-13).

Claim 14 further recites that said second housing is reusable (specification, page 4, third paragraph, line 16).

Claim 15 further recites a sampling instrument comprising a disposable housing (specification, page 4, third paragraph, lines 15-16) comprising a needle arranged for protrusion therefrom, said needle being adapted to draw therethrough a fluid (specification, page 3, last paragraph, lines 27-28); a reagent disposed in said disposable housing in fluid communication with said needle, capable of producing an optically-sensible reaction with a fluid (specification, page 3, last paragraph, lines 30-33); an optical sensor disposed in said disposable housing adapted to sense said optically-sensible reaction (specification, page 3, last paragraph, lines 33-34); a first optical waveguide in said disposable housing connected to said optical sensor (specification, page 4, first paragraph, lines 1-2) and to a first optical connector (specification, page 4, third paragraph, lines 13-15); and a processor disposed in a reusable housing in communication with said optical sensor adapted to process a signal from said optical sensor (specification, page 4, first paragraph, lines 1-2), said signal being a function of said optically-sensible reaction (specification, page 4, first paragraph, line 4), wherein said processor comprises a microprocessor and a photodiode (specification, page 4, first paragraph, lines 4-5), said processor being connected to a second optical waveguide disposed in

said reusable housing (specification, page 4, third paragraph, line 12), said second optical waveguide being connected to a second optical connector which mates with said first optical connector so as to effect optical communication between said processor and said optical sensor (specification, page 4, third paragraph, lines 13-15), wherein said photodiode is adapted to convert light emission transmitted thereto from said optical waveguide to a current (specification, page 4, first paragraph, lines 5-6), and a fluid pump disposed in said reusable housing in fluid communication with said needle adapted to pump a biological fluid through said needle (specification, page 4, fourth paragraph, lines 17-19), wherein said disposable housing comprises a waste receptacle for storing therein waste products of said optically-sensible reaction (specification, page 4, fifth paragraph, lines 20-21), and a display in communication with said processor (specification, page 4, first paragraph, lines 6-7).

Claim 16 further recites a light source adapted to transmit a light beam to said optically-sensible reaction (specification, page 4, last paragraph, line 29-31).

Claim 17 further recites that said light source is a source of coherent light (specification, page 4, last paragraph, line 29).

Claim 18 further recites said light source is a source of non-coherent light (specification, page 4, last paragraph, line 30).

Claim 19 further recites that said light source is disposed in said second housing and is adapted to transmit the light beam to said optically-sensible reaction via said second optical waveguide to said first optical waveguide, via said second optical connector which mates with said first optical connector (specification, page 4, last paragraph, line 29-31 and page 4, third paragraph, lines 13-15).

Claim 20 further recites that said optical sensor comprises a surface plasmon resonance sensor (specification, page 4, last paragraph, line 34).

Claims 1, 5-10 and 12-19 stand rejected under 35 USC §103(a) as being unpatentable over Shain et al (US 6027459), Douglas et al. (US 5951492), Moerman et al (US 6706159) or Stiene et al. (US 2004/0096959) in view of Eason et al (5186897) alone or further in view of Tenerz et al (US 4941473).

Claim 20 stands rejected under 35 USC §103(a) as being unpatentable over Shain et al (US 6027459), Douglas et al. (US 5951492), Moerman et al (US 6706159) or Stiene et al. (US 2004/0096959) in view of Eason et al (5186897) alone or further in view of Tenerz et al (US 4941473), as applied above, and further in view of Stanton et al (US 2004/0219523).

(vi) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Appellant contends that the remaining issues on appeal are as follows:

1. Whether Claims 1, 5-10 and 12-19 are unpatentable under 35 USC §103(a) over Shain et al (US 6027459), Douglas et al. (US 5951492), Moerman et al (US 6706159) or Stiene et al. (US 2004/0096959) in view of Eason et al (5186897) alone or further in view of Tenerz et al (US 4941473).

2. Whether Claim 20 is unpatentable under 35 USC §103(a) over Shain et al (US 6027459), Douglas et al. (US 5951492), Moerman et al (US 6706159) or Stiene et al. (US 2004/0096959) in view of Eason et al (5186897) alone or further in view of Tenerz et al (US 4941473), as applied above, and further in view of Stanton et al (US 2004/0219523).

As to Issue 1

Claims 1, 5-10 and 12-19 on appeal are grouped together.

As to Issue 2

Claim 20 on appeal is not grouped with other claims.

(vii) ARGUMENT

i. There are no rejections under 35 USC §112, first paragraph.

ii. There are no rejections under 35 USC §112, second paragraph.

iii. There are no rejections under 35 USC §102.

iv. Rejections under 35 USC §103(a)

Issue 1– Whether the rejection of claims 1, 5-10 and 12-19 under 35 U.S.C. § 103(a) is proper

Claims 1, 5-10 and 12-19 stand rejected under 35 USC §103(a) as being unpatentable over Shain et al (US 6027459), Douglas et al. (US 5951492), Moerman et al (US 6706159) or Stiene et al. (US 2004/0096959) in view of Eason et al (5186897) alone or further in view of Tenerz et al (US 4941473).

Appellant respectfully traverses these rejections. The optical waveguide in Eason et al. is used in a different manner than the instant invention. Eason et al. does not teach using an optical waveguide to optically connect the optical sensor to the processor. Instead, Eason et al. teaches using the optical waveguide as the place where the reaction takes place and uses an external fluorescence measuring device to measure the fluorescence created in the optical waveguide. The fluorescence measuring device is not connected to the optical waveguide. In contrast, in the present invention, the optical waveguides optically connect the optical sensor to the processor. This is entirely different from Eason et al.

Examiner has responded to the above as follows:

> Applicant's traverse the application of Easton et al. stating this reference fails to teach the claimed connection to the optical waveguide. This is not convincing because Easton et al. is only used to teach the advantages of using an optical waveguide. The Office maintains Shain et al. (USP 6,027,349), Douglas et al. (USP 5,951,492), Moerman et al. (USP 6,706,159) and Stiene et al. all teach the claimed attachment to the processor.

This is respectfully traversed. Appellant will show one-by-one, that none of the cited art has the feature of the processor as claimed in the instant invention, i.e., "a processor disposed in a second

housing in communication with said optical sensor adapted to process a signal from said optical sensor, said signal being a function of said optically-sensible reaction, wherein said processor comprises a microprocessor and a photodiode, said processor being connected to a second optical waveguide disposed in said second housing, said second optical waveguide being connected to a second optical connector which mates with said first optical connector so as to effect optical communication between said processor and said optical sensor, wherein said photodiode is adapted to convert light emission transmitted thereto from said optical waveguide to a current".

1. Shain only mentions a processor once in col. 15, lines 41-56: "The electronics 20 may incorporate a microprocessor or microcontroller. The function of the electronics 20 is to switch power on and off to operate the various components in the apparatus. These components include, but are not limited to, the vacuum pump 14. The electronics 20 can also be use to switch power on and off to operate components in alternative embodiments, e.g., heating elements, lancets, indicating devices, and valves. Electronics suitable for this invention is the "TATTLETALE MODEL 5 F" controller/data logger, commercially available from Onset Computer Corporation, 536 MacArthur Blvd. P.O. Box 3450, Pocasset, Mass. 02559-3450. Auxiliary electronic devices, such as power transistors, pressure monitors, and OP-Amps (operational amplifiers), may also be required in order to provide an interface between the controller and the operational components."

With the utmost respect, the electronics 20 has nothing to do with the claimed feature of "process **a signal from said optical sensor, said signal being a function of said optically-sensible reaction**, wherein said processor comprises a microprocessor and a photodiode."

2. Douglas et al. never even describes a processor.

3. Moerman et al. only mentions a processor once in col. 9, lines 35-56: "FIG. 10 shows a schematic representation of the electronics which can [be] incorporated in a device in accordance with the invention. As shown, input signals are provided from the sensors and from any included skin-contact or sufficient-sample detector systems to a signal processing system. These signals are transmitted via analog circuitry to a processor which performs data analysis. This processor provides a signal to display driver which is connected (via a wired or wireless connection) to an output display. The processor may also provide a signal via a wired or wireless connection to an alarm generator. The display and the alarm generator together constitute the output portion of the device. The data analysis processor also communicates with a memory device, for example an EEPROM, in

which information including calibration information and previous results may be stored. A timer is also provided which is activated by the data analysis software. This timer provides functional output signals to control a steeper motor (for rotating the sensor disk or spindle) and a vacuum generator (if present). Values from the timer may also be stored in the memory EEPROM for utilization by the data analysis processor."

With the utmost respect, this processor has nothing to do with the claimed feature of "process a **signal from said optical sensor, said signal being a function of said optically-sensible reaction**, wherein said processor comprises a microprocessor and a photodiode."

4. Stiene et al. only mentions a processor once in paragraph [0154]: "The chip 400 has an edge connector 401 for electrically connecting electrodes (as will be described) to a controller (not shown). A controller can contain logic, memory and processors for controlling the electronics of the chip 400 and optionally displaying any outputs (as, for example, the function and operation of controller 102 in FIG. 3)."

With the utmost respect, this processor has nothing to do with the claimed feature of "process a **signal from said optical sensor, said signal being a function of said optically-sensible reaction**, wherein said processor comprises a microprocessor and a photodiode."

Thus, the rejections are respectfully deemed overcome.

Issue 2– Whether the rejection of claim 20 under 35 U.S.C. § 103(a) is proper

Claim 20 stands rejected under 35 USC §103(a) as being unpatentable over Shain et al (US 6027459), Douglas et al. (US 5951492), Moerman et al (US 6706159) or Stiene et al. (US 2004/0096959) in view of Eason et al (5186897) alone or further in view of Tenerz et al (US 4941473), as applied above, and further in view of Stanton et al (US 2004/0219523).

As explained above in Issue 1, claims 1 and 16 are respectfully deemed patentable over the cited art. It follows that claim 20 is also deemed patentable over the cited art by virtue of its dependency on claim 16 which depends on claim 1.

Furthermore, Examiner states in the final rejection regarding Stanton, the following:

Applicant state Stanton et al. does not teach waveguides in combination with SPR. The Office has stated above Stanton et al. teach in paragraph [0351] it is known to incorporate biosensors into fiber optic waveguides and in paragraph[0138] real time data is generated by SPR sensor systems as shown in figures 67C and 67D. The Office maintains these teachings are sufficient to show that both waveguides and SPR are known in the art.

This is respectfully traversed. The SPR sensor system of paragraph [0138] has nothing to do with the **optical** sensor comprising a surface plasmon resonance sensor as claimed in claim 20. The SPR sensor system of paragraph [0138] is described as follows:

"[0138] FIG. 67 shows a schematic diagram of the integrated SPReeta SPR sensor module (FIG. 67A), as well as the nucleic acid (hammerhead ribozyme) sensor molecule that is immobilized on the gold SPR layer (FIG. 67B). FIGS. 67C and 67D show typical real-time data generated by the SPR sensor system during sensor loading and target analyte-induced cleavage, respectively."

It is respectfully pointed out that there is no mention here at all of an optical sensor. Thus, the rejection is respectfully deemed overcome.

CONCLUSION

For the reasons given above, pending claims are allowable and reversal of the Examiner's rejections is respectfully requested.

Respectfully submitted,

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(viii) CLAIMS APPENDIX

Claims involved in the Appeal:

1. A sampling instrument comprising:

a first housing comprising a needle arranged for protrusion therefrom, said needle being adapted to draw therethrough a fluid;

a reagent disposed in said first housing in fluid communication with said needle, capable of producing an optically-sensible reaction with a fluid;

an optical sensor disposed in said first housing adapted to sense said optically-sensible reaction;

a first optical waveguide in said first housing connected to said optical sensor and to a first optical connector; and

a processor disposed in a second housing in communication with said optical sensor adapted to process a signal from said optical sensor, said signal being a function of said optically-sensible reaction, wherein said processor comprises a microprocessor and a photodiode, said processor being connected to a second optical waveguide disposed in said second housing, said second optical waveguide being connected to a second optical connector which mates with said first optical connector so as to effect optical communication between said processor and said optical sensor, wherein said photodiode is adapted to convert light emission transmitted thereto from said optical waveguide to a current.

5. The sampling instrument according to claim 1, wherein said first housing is disposable.

6. The sampling instrument according to claim 1, further comprising a fluid pump in fluid communication with said needle adapted to pump a biological fluid through said needle.

7. The sampling instrument according to claim 1, further comprising a fluid pump in fluid communication with said needle adapted to pump a biological fluid through said needle, wherein said fluid pump is disposed in said second housing.

8. The sampling instrument according to claim 1, wherein said first housing further comprises a waste receptacle for storing therein waste products of said optically-sensible reaction.

9. The sampling instrument according to claim 1, wherein said needle is retractable into said first housing.

10. The sampling instrument according to claim 1, further comprising a display in

communication with said processor.

12. The sampling instrument according to claim 1, further comprising at least one of a transmitter and a receiver for wireless communication with an external device.

13. The sampling instrument according to claim 1, wherein said first and second housings together form an elongate housing.

14. The sampling instrument according to claim 1, wherein said second housing is reusable.

15. A sampling instrument comprising:

a disposable housing comprising a needle arranged for protrusion therefrom, said needle being adapted to draw therethrough a fluid;

a reagent disposed in said disposable housing in fluid communication with said needle, capable of producing an optically-sensible reaction with a fluid;

an optical sensor disposed in said disposable housing adapted to sense said optically-sensible reaction;

a first optical waveguide in said disposable housing connected to said optical sensor and to a first optical connector;

a processor disposed in a reusable housing in communication with said optical sensor adapted to process a signal from said optical sensor, said signal being a function of said optically-sensible reaction, wherein said processor comprises a microprocessor and a photodiode, said processor being connected to a second optical waveguide disposed in said reusable housing, said second optical waveguide being connected to a second optical connector which mates with said first optical connector so as to effect optical communication between said processor and said optical sensor, wherein said photodiode is adapted to convert light emission transmitted thereto from said optical waveguide to a current; and

a fluid pump disposed in said reusable housing in fluid communication with said needle adapted to pump a biological fluid through said needle, wherein said disposable housing comprises a waste receptacle for storing therein waste products of said optically-sensible reaction, and a display in communication with said processor.

16. The sampling instrument according to claim 1, further comprising a light source adapted to transmit a light beam to said optically-sensible reaction.

17. The sampling instrument according to claim 16, wherein said light source is a source of

coherent light.

18. The sampling instrument according to claim 16, wherein said light source is a source of non-coherent light.

19. The sampling instrument according to claim 16, wherein said light source is disposed in said second housing and is adapted to transmit the light beam to said optically-sensible reaction via said second optical waveguide to said first optical waveguide, via said second optical connector which mates with said first optical connector.

20. The sampling instrument according to claim 16, wherein said optical sensor comprises a surface plasmon resonance sensor.

(ix) EVIDENCE APPENDIX

NONE

(x) RELATED PROCEEDINGS APPENDIX

In accordance with 37 CFR §41.37(c)(1)(ii), Appellant advises the Board of Patent Appeals and Interferences (the "Board") that there are no other pending appeals, which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the instant appeal.